

**6 510(k) Summary**

This summary of the 510(k) premarket notification for the Concentric Hydrophilic Guidewire™ is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**6.1 Manufacturer**

Concentric Medical Inc.  
2585 Leghorn Street  
Mountain View, CA. 94043  
Telephone: (650) 938-2100  
Registration #: To be obtained

**6.2 Contact Person**

Linda Bradley  
Senior Regulatory Affairs Specialist

**6.3 Date Prepared**

September 29, 2000

**6.4 Classification**

Catheter Guidewire, 21CFR 870.1330 – Class II

**6.5 Trade Name**

Concentric Hydrophilic Guidewire™

**6.6 Generic/Common Name**

Catheter Guidewire

**6.7 Predicate Devices**

Micro Therapeutics SilverSpeed™ Hydrophilic Guidewire (K993257)  
Cordis Endovascular Systems, Inc. AGILITY™ Steerable Guidewires (K001033)

**6.8 Intended Use**

The Concentric Hydrophilic Guidewire™ is indicated for general intravascular use to aid in the selective placement of catheters in the coronary, peripheral, visceral and cerebral vasculature.

**6.9 Product Description**

The Concentric Hydrophilic Guidewire consists of a flexible, tapered core wire that decreases in outer diameter from the proximal to the distal end. The hydrophilic coating reduces friction during use. The radiopaque distal coil facilitates fluoroscopic visualization.

**6.10 Substantial Equivalence**

The Concentric Hydrophilic Guidewire is intended for use in interventional radiological procedures. It is substantially equivalent to other devices currently on the market for use in interventional radiological procedures. The Concentric Hydrophilic Guidewire is equivalent to the Micro Therapeutics SilverSpeed™ Hydrophilic Guidewire (K993257) and the Cordis Endovascular Systems, Inc. AGILITY™ Steerable Guidewires (K001033). The Concentric Hydrophilic Guidewire is substantially equivalent to these predicate devices with regards to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Concentric Hydrophilic Guidewire and its predicate devices do not raise any new issues of safety or effectiveness.

**6.11 Testing in Support of Substantial Equivalence**

Performance testing and animal testing have been conducted and the results of the testing verified that the Concentric Hydrophilic Guidewire performs as designed and is suitable for its intended use.

**6.12 Conclusion**

As contained in this 510(k) summary, the Concentric Hydrophilic Guidewire is substantially equivalent to the predicate device identified in regards to device design, intended use, patient population and anatomical site.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 16 2001

Mr. Kevin F. MacDonald  
Concentric Medical, Inc.  
2585 Leghorn Street  
Mountain View, CA 94043

Re: K003084  
Concentric Hydrophilic Guidewire™  
Regulation Number: 870.1330  
Regulatory Class: II (two)  
Product Code: 74 DQX  
Dated: March 23, 2001  
Received: March 26, 2001

Dear Mr. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

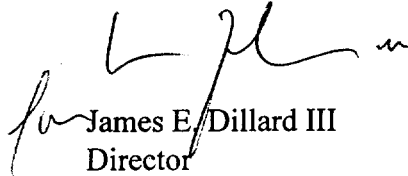
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the printed name and title.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**5 Statement of Indications for Use****INDICATIONS FOR USE**510(k) Number (if known): K003084

Device Name: Concentric Hydrophilic Guidewire™

Indications for Use:

The Concentric Hydrophilic Guidewire™ is indicated for general intravascular use to aid in the selective placement of catheters in the coronary, peripheral, visceral and cerebral vasculature.

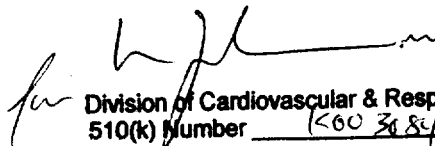
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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K003084